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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|----------------|----------------------|-------------------------|------------------|--|
| 09/472,067 | 12/23/1999 | A-Li W. Hu | 0942.4340002 | 8277 | |
| 26111 7 | 590 05/28/2002 | | | • | |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W., SUITE 600 WASHINGTON, DC 20005-3934 | | | EXAMINER | | |
| | | | ZARA, JANE J | | |
| | | | ART UNIT | PAPER NUMBER | |
| | | | 1635 | 18 | |
| | | | DATE MAILED: 05/28/2002 | _ | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application | No. | Applicant(s) | <u> </u> | | | | |
|---|--|---------------|--|----------|--|--|--|--|
| • | | 110. | | | | | | |
| Office Action Summary | 09/472,067 | | HU ET AL. | | | | | |
| Office Action Summary | Examiner | | Art Unit | | | | | |
| The MAN INC DATE of this communication of | Jane Zara | over sheet u | 1635 | ldross - | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | | | |
| 1) Responsive to communication(s) filed on <u>25</u> | 1) Responsive to communication(s) filed on <u>25 February 2002</u> . | | | | | | | |
| 2a) This action is FINAL . 2b) ⊠ 7 | This action is n | on-final. | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Disposition of Claims | | | | | | | | |
| 4) Claim(s) 1-34 is/are pending in the application. | | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | | |
| 6)⊠ Claim(s) <u>1-21 and 23-34</u> is/are rejected. | | | | | | | | |
| 7)⊠ Claim(s) <u>22</u> is/are objected to. 8)⊡ Claim(s) are subject to restriction and. | /or election rec | uirement | | | | | | |
| Application Papers | , or cicotion rec | quirernent. | | | | | | |
| 9) The specification is objected to by the Examir | ner. | | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ acc | cepted or b) 🗌 o | bjected to by | the Examiner. | | | | | |
| Applicant may not request that any objection to | | | | | | | | |
| 11) The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | | |
| a) All b) Some * c) None of: | | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | | |
| Attachment(s) | | | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s | | | w Summary (PTO-413) Paper Note of Informal Patent Application (P | | | | | |

File

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DETAILED ACTION

This Office action is in response to the communications filed March 20, 2001 and

February 25, 2002, Paper Nos. 8 and 14.

Claims 1-34 are pending in the instant application.

The final Office action mailed October 25, 2001, is vacated in favor of the instant Office

action.

The text of those sections of Title 35, U.S. Code not included in this action can be found

in a prior Office action.

Response to Arguments

Maintained Rejections

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention, for the reasons of record set forth in the Office action mailed November 20, 2000,

Paper No. 6.

Applicant's arguments filed March 20, 2001 have been fully considered but they are not

persuasive. Applicants argue that the term of claim 1, lines 12-13 which reads: "nucleotide

compositions of $(X_1 X_2)_n$ and $(Y_1 Y_2)_n$ are substantially identical", and the term of claim 2,

lines 15-16 which reads: "nucleotide compositions of $(X_1 X_2)_n A_m$ and $B_m(Y_1 Y_2)_n$ are

substantially identical" are supported adequately in the instant disclosure and that one of ordinary

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skill in the art could easily determine the metes and bounds of these terms. Contrary to Applicants' assertions, it is not clear whether the claimed nucleotides are to be compared for substantial identity between the strands or between nucleotides of a particular strand (i.e. between X's, between Y's, between \underline{X} 's and \underline{Y} 's, between \underline{X} 's and \underline{Y} 's, between \underline{X} 's plus \underline{X} 's and \underline{Y} 's plus \underline{Y} 's...). Appropriate clarification is requested.

Claims 1-21 and 23-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Singer for the reasons set forth in the Office action mailed November 20, 2000, Paper No. 6.

Applicant's arguments filed April 23, 2001, Paper No. 8, have been fully considered but they are not persuasive. Applicants argue that the claimed invention is distinct from the previously cited Singer reference because Singer does not teach two strands of double stranded nucleic acid molecules which are substantially identical in their base compositions in the bottom and top strands. Contrary to Applicants' assertions, Singer does teach nucleic acid molecules which comprise two or more repeating sequences separated by a restriction site, which repeating sequences comprise single identical or non-identical nucleotides and their complement, which repeating sequences conform to the formulae:

 $(X_1X_2)_n$ (and its complement), whereby X_1 and X_2 are single nucleotides and n is an integer from 1 to 1 x 10¹⁰; or $(X_1X_2)_nA_m$ (and its complement $B_m(Y_1Y_2)_n$, whereby X_1 , X_2 , A and B are single nucleotides, n is an integer from 1 to 1 x 10¹⁰, and m is an integer between 1 and 100, wherein two or more repeating sequences are separated by restriction endonuclease cleavage into repeats including monomers through pentamers. The examples provided in the instant specification of

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substantially identical base compositions comprise approximately 60 % sequence identity (See page 8 of the specification, lines 16-24). In the examples provided by Singer, nucleic acid molecules comprising approximately 60% sequence identity between the bottom and top strands are listed (See especially element design *EP/SmP* in Table 1 of Singer, in columns 11 and 12). Therefore the examples provided by Singer anticipated the claimed invention.

Claim Objections

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JΖ

May 24, 2002

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